

DECLARATION OF CONFORMITY

This declaration is made in accordance with the requirements of Annex VII of the Directive 93/42/EEC

Manufacturer: Ansell Healthcare Europe N.V.

Classification: Class IIa

GMDN Code & Definition: 47178 – Hevea-latex surgical glove, non-powdered, non-antimicrobial

Brand Names:

Code	Product Name	Glove Size	Region
330101055	ENCORE Latex Textured	5.5	EMEA
330101060	ENCORE Latex Textured	6	EMEA
330101065	ENCORE Latex Textured	6.5	EMEA
330101070	ENCORE Latex Textured	7	EMEA
330101075	ENCORE Latex Textured	7.5	EMEA
330101080	ENCORE Latex Textured	8	EMEA
330101085	ENCORE Latex Textured	8.5	EMEA
330101090	ENCORE Latex Textured	9	EMEA
5785000	ENCORE® Latex Textured	5.5	NA/LAC
5785001	ENCORE® Latex Textured	6	NA/LAC
5785002	ENCORE® Latex Textured	6.5	NA/LAC
5785003	ENCORE® Latex Textured	7	NA/LAC
5785004	ENCORE® Latex Textured	7.5	NA/LAC
5785005	ENCORE® Latex Textured	8	NA/LAC
5785006	ENCORE® Latex Textured	8.5	NA/LAC
5785007	ENCORE® Latex Textured	9	NA/LAC

Conforms to the applicable essential requirements of Annex I of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47 /EEC.

With production systems certified, where applicable, through the British Standards Institution, Notified Body Number 2797, Certificate Number CE 01537 under Annex V of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47/EEC.



Signed on behalf of the Manufacturer **Ansell Healthcare Europe NV**

A handwritten signature in blue ink, appearing to read "Samantha Marshall", written over a horizontal line.

Riverside Business Park - Block J
Bld Internationalelaan 55
B-1070 Brussels
BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs EMEA & APAC
Date: 27 November 2020
Version No: MED\ENLATTEX\003